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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,196	07/23/2003	Guido Guglielmi	03-276 (US01)	1254

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VISTA IP LAW GROUP LLP
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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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04/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,196	Applicant(s) GUGLIELMI ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-52, 54, 55, 57 and 59-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-52, 54, 55, 57 and 59-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/09/2008 has been entered.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 29-52, 54-55, and 59-73 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body in combination with the device, e.g. lines 2 and 3 of claims 29 and 67, "the catheter being inserted into a vascular cavity in the body" (Note: these are only a few examples of where part of the human body is positively recited. Many more instances exist throughout the claims). It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ

636 (CCPA 1970). For examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 29-31, 37-38, 43-45, 47-52, 54, 59-61, 64-65, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**).

Claims 29-31, 37-38, 43-45, 47, 54, 59-61, 64-65, and 72: Ogawa discloses a system for positioning an implant or vaso-occlusive coil **16** comprised of platinum in a body including a catheter **20** having a proximal end and a distal end, the catheter being inserted into a vascular cavity in the body, a delivery member or wire **10** having a conductive wire, an insulative member **25**, a temporary connection **15** joined to a distal end of the delivery member, and an electrical measurement device ("counter electrode") **23**, wherein the electrical measurement device is configured to monitor an electrical condition ("impedance reducing phenomenon") related to a position of the temporary connection while the temporary connection is joined to the delivery member and joined to the implant through the insulative member, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location at or

beyond the distal end of the catheter as the delivery member is advanced through the catheter, the electrical measurement device configured to generate an output signal (monitoring the magnitude of impedance between the delivery wire and the electrical measurement device) while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating the temporary connection, joined to the implant, has reached the predetermined location, and subsequently allowing the user to initiate breaking of the temporary connection by application of heat and releasing the implant (see abstract, Figures 5-6, col. 6, lines 34-61, col. 7, line 54 to col. 8, line 15, col. 9, lines 35-52). Also disclosed is a visual indicator (monitored change in impedance) which is illuminated after the electrical condition has changed while the implant is joined to the temporary connection.

Ogawa discloses the claimed device except for the insulative member being positioned between and connecting the temporary connection and the implant. Ogawa discloses that the insulative member is proximal to the temporary connection and implant (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the insulative member between the temporary connection and the implant, since applicant has not specifically disclosed that having the insulative member between the temporary connection and implant solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the insulative member being between the temporary connection and the implant.

Claims 48-50: Although Ogawa does not disclose the coil having a bio-reactive material coating or the coil being a non-bio-reactive polymer coil (however teaching that

the implant "may carry or hold suitable substances," col. 6, lines 59-61), it would have been obvious to one of ordinary skill in the art to provide the claimed materials, since it was known in the art that a coating of bio-reactive material may aid in the endovascular embolism or occlusion and non-bio-reactive polymer coils can remain longer within the body without having to be surgically removed.

Claims 51-52: Ogawa discloses the claimed device except for the implant comprising a stent or a filter. It would have been obvious to one of ordinary skill in the art to provide a stent or a filter as the implant, since it was known in the art that vaso-occlusion is commonly achieved by filters and stents.

4. Claims 32-36, 41-42, 46, 55, 57, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Scheldrup** (U.S. Patent No. **5,669,905**).

Claims 32-34, 36, 46: Ogawa discloses the claimed device except for the temporary connection comprising an electrolytic connection, the connection comprising a stainless steel portion of the delivery member that is exposed to the blood in a vascular cavity in the body, the electrical monitoring device being separate from the power supply, and the coil comprising a Guglielmi Detachable Coil (GDC).

Scheldrup teaches a temporary connection comprising an electrolytic connection, the connection comprising a stainless steel portion of the delivery member that is exposed to the blood in a vascular cavity in the body, and the electrical monitoring device **300** being separate from the power supply which provides electrical current

Art Unit: 3731

through the delivery member to corrode a portion of the temporary connection (Figures 6-7, col. 4, lines 34-42, col. 5, lines 1-3 and 49-55). Scheldrup also teaches using a Guglielmi Detachable Coil (GDC) (col. 12, lines 19-33). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ogawa by having a GDC, an electrolytic connection, and an electrical monitoring device separate from the power supply, as taught by Scheldrup, since they are well known in the art and facilitate quick detachment of the implant.

Claim 35: Ogawa discloses a power supply **24** including the electrical monitoring device (col. 7, lines 54-61).

Claims 41-42: Ogawa discloses the claimed device, including the electrical condition comprising an impedance, except for the electrical condition comprising a current or voltage.

Scheldrup teaches that current may be monitored as an electrical condition (col. 12, lines 42-46). It would have been obvious to one of ordinary skill in the art at the time of invention to monitor current as an electrical condition, as taught by Scheldrup, to Ogawa in order to effectively detach an implant from an electrolytic connection and generate an output signal.

Claims 55, 57, and 66: Ogawa discloses the claimed device, except for an audio indicator, a controller, and the electrical monitoring device comprising a volt/current meter.

Scheldrup teaches an audio indicator, an electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator

can be activated after an electrical condition has changed (col. 10, lines 30-44) and the electrical monitoring device comprising a volt/current meter (Figures 4-6).. It would have been obvious to one of ordinary skill in the art at the time of invention to provide an audio indicator and volt/current meter, as taught by Scheldrup, to Ogawa in order to facilitate signaling to the physician when positioning the implant.

Scheldrup also teaches an output signal being provided to a controller **300**, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49).

5. Claims 67-71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Scheldrup** (U.S. Patent No. **5,669,905**).

Claims 67, 69-71 and 73: Ogawa discloses the claimed device, as claimed in paragraph 4 above, including the electrical condition comprising an impedance, except for the electrical condition comprising a current or voltage.

Scheldrup teaches that current may be monitored as an electrical condition (col. 12, lines 42-46). It would have been obvious to one of ordinary skill in the art at the time of invention to monitor current as an electrical condition, as taught by Scheldrup, to Ogawa in order to effectively detach an implant from an electrolytic connection and generate an output signal.

Art Unit: 3731

Claim 68: Ogawa discloses the claimed device except for the temporary connection comprising an electrolytic connection, the connection comprising a stainless steel portion of the delivery member that is exposed to the blood in a vascular cavity in the body, the electrical monitoring device being separate from the power supply, and the coil comprising a Guglielmi Detachable Coil (GDC).

Scheldrup teaches a temporary connection comprising an electrolytic connection, the connection comprising a stainless steel portion of the delivery member that is exposed to the blood in a vascular cavity in the body, and the electrical monitoring device **300** being separate from the power supply which provides electrical current through the delivery member to corrode a portion of the temporary connection (Figures 6-7, col. 4, lines 34-42, col. 5, lines 1-3 and 49-55). Scheldrup also teaches using a Guglielmi Detachable Coil (GDC) (col. 12, lines 19-33). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ogawa by having a GDC, an electrolytic connection, and an electrical monitoring device separate from the power supply, as taught by Scheldrup, since they are well known in the art and facilitate quick detachment of the implant.

6. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Guglielmi** (U.S. Patent No. **5,569,245**).

Claim 39: Ogawa discloses the claimed device, as discussed above, except for the temporary connection comprising a temporary connection that is breakable by application of radio frequency (RF) radiation.

Guglielmi teaches a temporary connection that is breakable by application of radio frequency (RF) radiation (col. 3, lines 10-20). It would have been obvious to one of ordinary skill in the art to provide a temporary connection broken by heat and RF radiation, as taught by Guglielmi, to Ogawa, since it was known in the art that RF radiation is an effective detachment sources and commonly breaks connections, joints, or attachments in surgical devices.

7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Sepetka** (U.S. Patent No. **5,814,062**).

Claim 40: Ogawa discloses the claimed device, except for the temporary connection comprising a temporary connection that is hydraulically broken.

Sepetka teaches a temporary connection that is hydraulically broken (col. 3, lines 10-26). It would have been obvious to one of ordinary skill in the art to provide a temporary connection that is hydraulically broken, as taught by Sepetka, to Ogawa,

since it was known in the art that fluid pressure is commonly used to disconnect temporary detachments between embolic coils and delivery members.

8. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ogawa** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Cheng** (U.S. Patent No. **6,296,636**).

Claims 62-63: Ogawa discloses the claimed device, as discussed above, except for comparing a reference current with a second current that is generated, the second current being larger than the reference current, or the electrical measurement device including a comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal the measured current is larger than the threshold current.

Cheng teaches an electrical measurement device including a current measurement device configured to monitor the electrical current and a comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current is larger than the threshold current – the output indicating limiting power (col. 5, lines 15-34). Cheng teaches limiting power during electrosurgery to avoid overcurrent or sparks that may occur, which is effectively prompted by using reference and measured currents (col. 3,

lines 48-55). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ogawa by providing a comparison circuit, as taught by Cheng, in order to obtain a desired output signal, which may limit power during electrosurgery to avoid overcurrents or sparks, which is effectively prompted by using reference and measured currents.

Response to Arguments

9. Applicant's arguments with respect to claims 29-52, 54-55, 57, and 59-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731